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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,367	03/10/2004	Janel E. Young	ETH5095CIP	4470

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
10/31/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/797,367	YOUNG ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-19,21-25,27,28,30-37 and 39-41* is/are pending in the application.

4a) Of the above claim(s) *1-13,17-19 and 35-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 16, 21-25, 27, 28, 30-32, 34 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 7/08/08; power of attorney filed 6/24/08. Claims 15, 29 and 33 are canceled. Claims 14, 16, 21, 28, 30, 35-37 and 39-41 are amended. Claims 1-14, 16-19, 21-25, 27, 28, 30-32, 34-37 and 39-41 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 14, 21, 24, 25, 28, 31, 32 and 39 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (US 6,239,177) according to the rejections of record and reiterated below with modification to address the amendment to the claims.

3. Claims 14 and 28 are amended to incorporate the limitations of canceled claims 15 and 29 except for the limitations of microcapsules, microspheres, liposomes, lipid foams, solutions, compositions, osmotic pumps and gels. Claims 16, 21, 30 and 39 are also amended to exclude some of the polymers present in the prior art of record.

Mori discloses external tranilast composition (abstract; column 2, lines 39-43) comprising tranilast, dissolution medium (column3, line 54 to column 4, line 24), polymers such

as propylene glycol (column 4, line 65), polyvinyl alcohol, polyethylene glycol, polyacrylate, naturally occurring polysaccharides, gelatin, gum Arabic, polyester (column 5, lines 22-27, 62) with the suggestion that these polymer can be used alone or in combination of two or more thereof (column 5, lines 27 and 28); Mori's composition is in the form of a patch or film (column 5, lines 13, 58-65; Examples 1 and 2); the composition of Mori and the polymer carrier meet the requirements of claims 14 and 28 in the form of a patch or film and claims 21 and 39 are met when the barrier comprises gelatin or species of starch as in Example 1. Claims 24, 25 and 31 and 32 are directed to the properties/characteristic of the device so that the composition of Mori meets these claims.

Response to Arguments

4. Applicant's arguments filed 7/08/08 have been fully considered but they are not persuasive.

5. Applicant argues that Mori does not disclose barriers that can be film, foam, fibers or filaments. But applicant acknowledges that Mori teaches a patch that can be a film as evidenced by paragraphs [0809] and [0813] of US 20040053973; further more, Mori specifically contemplates composition/vehicle as a film (see column 5, lines 13, 58-65; Examples 1). Therefore, Mori contemplates the composition in the form of a patch or film.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 14, 16, 27, 28, 30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1) according to the rejections of record and reiterated herein below with modification to address the limitations of the amended claims.

Mori is described above as describing the composition in claims 14, 21, 24, 25, 28, 31, 32 and 39. When the barrier in Mori is polyester (see column 5, line 62), then claims 16 and 30 are rendered obvious because the lactides, glycolides and caprolactones of claims 16 and 30 are all polyesters. Mori describes that it has been found in the prior art that tranilast is found in the skin of keloid patients at about 8-10 μg/g (column 2, line 47) and suggests that tranilast concentration on skin after application to the skin would be higher that that previously observed (column 2, lines 57-60) but does not disclose the concentration of the tranilast in the composition in claims 27 and 34. However, given the general teaching of Mori regarding the use of the tranilast to treat keloid or allergic dermatitis, one having ordinary skill in the art at the time the

invention was made would have reasonable expectation of success in using an amount of the tranilast in the composition that would be effective to treat keloid or allergic dermatitis.

Response to Arguments

9. Applicant's arguments filed 07/08/08 have been fully considered but they are not persuasive.

10. Applicant argues that Mori is deficient because the art does not teach film or foam or fiber or filament. The examiner disagrees because applicant acknowledges that Mori teaches a patch that can be a film as evidenced by paragraphs [0809] and [0813] of US 20040053973; further more, Mori specifically contemplates composition/vehicle as a film (see column 5, lines 13, 58-65; Examples 1). Therefore, Mori contemplates the composition in the form of a patch or film.

11. Claims 14, 22, 23, 40 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1) in view of Pope et al. (US 5,948,822) for reasons of record and reiterated herein below.

Mori has been described above for disclosing the composition in claims 14, 21, 24, 25, 28, 31, 32 and 39. Mori's composition does not contain further therapeutic agents recited in claims 22, 23, 40 and 41. However, Pope discloses antiproliferative agent that reduces the hyperproliferative keloid formation (column 3, lines 12-34; column 5, lines 1, 2, 6 and 7). Given the general teachings of Mori and Pope, one having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success that the combined

compositions of Mori and Pope would be effective to reduce hyperproliferative keloid formation. See also *in re Kerkhoven*.

Response to Arguments

12. Applicant's arguments filed 07/08/08 have been fully considered but they are not persuasive.

13. Applicant argues that Pope fails to cure the deficiencies of Mori, which is that the claimed product is a film or foam or fiber or filament and that Pope also fails to teach any of these forms. The examiner disagrees because applicant acknowledges that Mori teaches a patch that can be a film as evidenced by paragraphs [0809] and [0813] of US 20040053973; further more, Mori specifically contemplates composition/vehicle as a film (see column 5, lines 13, 58-65; Examples 1). Therefore, Mori contemplates the composition in the form of a patch or film. Pope is relied upon for teaching the use antiproliferative agent for the reduction of the hyperproliferative keloid formation.

14. Claims 14, 16, 24, 25, 28, 30, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaji et al. (US 6,407,139).

Isaji discloses composition comprising tranilast (abstract; column 2, lines 25-52; column 3, lines 22-24), additives such as excipients, disintegrators, binders, lubricants, diluents, buffers, isotonicity agents, antiseptics, moistening agents, emulsifiers, dispersing agents, stabilizing agents and dissolving aids (column 4, lines 34-39) and polymers such as lactic acid, polyacrylamide, lactic acid-glycolic acid copolymer and polyvinylpyrrolidone when a sustained release preparation is desired (column 5, lines 1-7); the composition is formulated into dosage forms such as powders, granules, fine granules, dry syrup, tablets, **ointments**, injections and eye

drops (column 4, lines 30-33) with ointment and eye drops representing non-systemic administration although the claimed invention is directed to a delivery device for which the composition of Isaji is. Claims 24, 25, 31 and 32 are directed to the properties/characteristic of the device so that the composition of Isaji meets these claims. When polymers are lactides, claims 16 and 30 are met as the barrier and also meeting the barrier of claims 14 and 28. Isaji does not teach the forms of the product, namely, foam or film or fiber or filament. However, when an ointment is topical applied it is generally spread into film as evidenced by claims 1 and 16 of US 5,578,310. Therefore, taking the teaching of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that topically applying the ointment of Isaji would expected form a film as contemplated for topical delivery of tranilast.

15. Claims 14, 22, 23, 28, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaji et al. (US 6,407,139) in view of Akhtar et al. (US 5,432,163).

Isaji has been shown above to render obvious claims 14, 16, 24, 25, 28, 30, 31 and 32. Isaji acknowledges in the background that tranilast is used to treat conditions such as allergic disorders such as bronchial asthma, allergic rhinitis, **atopic dermatitis** and allergic conjunctivitis, and cutaneous disorders such as keloid and hypertrophic scar (column 2, lines 6-16). Isaji does not teach the presence other therapeutic agents with the tranilast. However, Akhtar discloses antiproliferative for treating **atopic dermatitis** (column 3, lines 45-57). Given the general teachings of Isaji and Akhtar, one having ordinary skill in the art at the time the

invention was made would have a reasonable expectation of success that topical application of the ointment of Isaji would be effective to treat atopic dermatitis according to Akhtar.

Response to Arguments

16. Applicant's arguments filed 07/08/08 as it applies to the current rejections have been fully considered but they are not persuasive.

17. Applicant argues that Isaji does not teach the forms of the product as recited in the amended claims. The examiner disagrees. The rejection is not an anticipatory rejection since the claims are amended. However, it is evidenced in the art that topical application of an ointment leads to the formation of film so that formation of film upon topical application would be reasonably expected.

Double Patenting

18. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 14-19, 21-25, 27-37 and 39-41 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 14-41 of copending Application No. 10/714,719 (US 20050106229). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

21. Claims 14-19, 21-25, 27-37 and 39-41 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-19, 21-24, 27-41 of copending Application No. 10/780,452 (US 20050181023) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997, abstract for reasons of record and reiterated herein below.

The compositions of copending claims 14-19, 21-24, 27-41 of application number 10/780,452 contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

22. Applicant's arguments filed 07/08/08 have been fully considered but they are not persuasive.

23. Applicant's indication that claims 14-41 may be canceled upon indication of allowable subject matter and applicant's willingness to file terminal disclaimer to overcome the obviousness type double patenting is acknowledged. However, the provisional obviousness type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the

applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance. The provisional double patenting will not also be kept in abeyance because applicant has not overcome the rejection.

24. **Other Matters**: Claim 21 depends on canceled claim 15. Correction is respectfully requested.

No claim is allowed

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618